Message

From: Rosen, Bailey [Rosen.Bailey@epa.gov]
Sent: 11/10/2020 9:20:41 PM
To: Bolen, Derrick [bolen.derrick@epa.gov]; Collazo Reyes, Yvette [CollazoReyes.Yvette@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Drinkard, Andrea [Drinkard.Andrea@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Fischer, David [Fischer.David@epa.gov]; Giddings, Daniel [giddings.daniel@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Hughes, Hayley [hughes.hayley@epa.gov]; Kaiser, Sven-Erik [Kaiser.Sven-Erik@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Kochis, Daniel [Kochis.daniel@epa.gov]; Labbe, Ken [Labbe.Ken@epa.gov]; Layne, Arnold [Layne.Arnold@epa.gov]; Lieberman, Paige [Lieberman.Paige@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]; Mills, Madeline [Mills.Madeline@epa.gov]; Nguyen, Khanh [Nguyen.Khanh@epa.gov]; OPS CSID CB [OPS_CSID_CB@epa.gov]; Richmond, Jonah [Richmond.Jonah@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Sullivan, Melissa [sullivan.melissa@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Vernon, Jennifer [Vernon.Jennifer@epa.gov]
Subject: OCSPP News for November 10, 2020

OCSPP News Round-Up

General EPA

- Politico Pro 11/10; Transition 2020: Obama alumni stack Biden EPA transition team

TSCA

- Chemical Watch 11/10; US EPA releases IRIS handbook for developing chemical assessments
- Chemical Watch 11/10; Special Chemical Watch podcast: US election (Podcast)
- Bloomberg Law 11/10; Biden's EPA Expected to Pass Limits on Some 'Forever Chemicals'
- Bloomberg Law 11/10; Biden to Emphasize Chemicals Concerns of 'Frontline' Communities
- Chemical & Engineering News 11/8; 1,4-Dioxane: Another forever chemical plagues drinking-water utilities
- E&E News 11/10; Biden plans PFAS rules, hazardous designation
- Inside TSCA 11/9; Bracing For Stricter TSCA, Chemical Industry Vows Cooperation With Biden
- Inside TSCA 11/9; After Biden Win, Environmentalists Push To Implement PFAS Pledges
- Inside TSCA 11/9; Environmentalists Fault EPA's Speedy Review For Second PV29 Evaluation
- Inside TSCA 11/9; EPA seeks small entity advice on HBCD risk management rule

Pesticides

- Bloomberg Law 11/9; Bayer-Roundup Judge Moves to Resume Cancer Trials in U.S. (2)
- Yahoo Finance 11/9; Bayer makes 'substantial progress' in Roundup cancer lawsuits, mediator says
- Treehugger 11/10; USDA Suggests Organic Is Overrated, but Not Everyone Agrees
- Progressive Farmer 11/10; Dicamba Labels Challenged
- The Albany Herald 11/10; Farmers relieved by EPA's dicamba ruling
- NC State University News 11/10; We Modified Crops to Kill Pests, and Pests Evolved to Adapt. Now What?

Blog/OpEd/Other

- B&C TSCAblog 11/10; EPA Seeks Participants for Small Business Review Panel on HBCD Risk Management Rulemaking
- National Law Review (B&C) 11/10; EPA Seeks Participants for Small Business Review Panel on HBCD Risk Management Rulemaking
- Environment Working Group 11/9; How Will the Biden Administration Tackle 'Forever Chemicals'?
- Mesothelioma Guide 11/10; Lung Cancer Awareness Month: A Plea to Ban Asbestos

++

Transition 2020: Obama alumni stack Biden EPA transition team

Alex Guillén, Politico Pro
https://subscriber.politicopro.com/energy/article/2020/11/transition-2020-obama-alumni-stack-biden-epa-transition-team-2017932

A number of former high-level EPA officials from the Obama administration are on the agency review team that will help President-elect Joe Biden's administration transition into power.

The team is led by Patrice Simms, vice president of litigation at Earthjustice. He formerly worked as a career attorney at EPA in the 1990s and early 2000s. He also spent time as the deputy assistant attorney general in the Justice Department's Environment and Natural Resources Division.

Obama administration alumni include Matt Fritz, who was chief of staff from 2015 to 2017 and is now at firm Latham & Watkins; Cynthia Giles, who spent eight years as EPA's enforcement chief and is now at the Harvard Environmental and Energy Law Program; Joseph Goffman, a top air adviser who now runs that Harvard program; Ken Kopocis, a top water official now at American University's law school; and Ann Dunkin, the former EPA chief information officer now at Dell Technologies.

Goffman played a key role in writing several major air regulations, including the Clean Power Plan, and Kopocis spent virtually his entire career working on battles over the scope of the Clean Water Act, ultimately drafting the Obama administration's Waters of the U.S. rule.

Other Obama alumni include Lisa Garcia, an environmental justice adviser who has since worked at Earthjustice and most recently the nonprofit Grist Magazine; Luseni Pieh, previously a White House liaison and deputy chief of staff; and Amanda Aguirre, the former acting director of public engagement and environmental education.

The team will include Michael McCabe, who served as deputy administrator for the final year of the Clinton administration. McCabe previously served on the Obama transition team in 2008.

Also on the list are Alejandra Núñez, a Sierra Club attorney, and Billie McGrane of the Pennsylvania Democratic Party.

All but McGrane are working on a volunteer basis, according to the Biden transition.

US EPA releases IRIS handbook for developing chemical assessments
Terry Hyland, Chemical Watch
https://chemicalwatch.com/177697/us-epa-releases-iris-handbook-for-developing-chemical-assessments

The US EPA has released the long-awaited draft handbook for the Integrated Risk Information System (IRIS), which lays out 13 steps and procedures for the programme's staff to develop each of its draft chemical assessments.

The IRIS programme conducts independent risk assessments to support the EPA's work on hazardous chemicals. The handbook, released today, is intended to set out consistent operating procedures on how the programme conducts its impartial reviews.

The draft lays out 13 sequential stages for developing a chemical assessment, from the initial scoping process for IRIS staff to follow:

- scoping;
- problem formulation;
- systematic review protocol;
- literature search, screening and inventory;
- refined evaluation plan;
- study evaluation;
- organise hazard review;

- data extraction and display;
- synthesis of human and animal studies;
- synthesis of mechanistic information;
- integration;
- hazard considerations and study selection for deriving toxicity values; and
- derive toxicity values.

Historical criticism

The handbook builds on recommendations from the National Academies of Sciences (NAS) and its principles of systematic review, according to the draft.

The NAS offered a stinging review of the programme's effectiveness in 2011. It softened its tone in 2018, noting "substantial progress" made by the programme in synthesising and integrating evidence.

The Government Accountability Office has criticised IRIS more recently, saying the programme lacks predictability.

Industry too has found fault with the IRIS programme, criticising it for a lack of transparency and a lack of productivity in assessing substances. Less than two years ago, the non-profit thinktank the Competitive Enterprise Institute (CEI) called for the programme to be scrapped entirely.

The American Chemistry Council offered a more optimistic tone after the handbook's release, calling it "an encouraging sign".

"We will review the document to ensure that it clearly describes how the agency evaluates the quality of scientific evidence and integrates human, animal and mechanistic data to draw scientifically defensible conclusions regarding human health hazard, based on up-to-date 21st century knowledge of modes of action," the chemical industry trade group said on 10 November.

Processes detailed

The handbook attempts to address some of these concerns, laying out the process for conducting studies of literature and research as well as the screening process for categorising and considering "potentially relevant supplemental material", and using machine-learning tools to assist in the literature screening process.

The handbook also outlines steps for evaluating scientific studies, with criteria development, testing and evaluation steps and an overall rating system. It also organises the hazard review evaluation process with an outline for the synthesis of evidence.

With the handbook's release, the EPA also announced a 90-day consultation period for the public and any interested parties to comment on the draft handbook.

Special Chemical Watch podcast: US election

Chemical Watch

https://chemicalwatch.com/177358/special-chemical-watch-podcast-us-election

Former senior EPA officials Robert Sussman, Erik Baptist and Jeff Morris speak to Chemical Watch

After a drawn out election week in the US, all eyes are on the White House to see how President Elect Joe Biden might use his executive powers to push ahead with his agenda through executive orders – a tool frequently utilised by Presidents Trump and Obama – as well as regulatory actions via federal agencies like the EPA.

And while the president-elect has laid out some of his priorities so far, Covid-19, economic recovery, racial justice and climate change, many questions remain over what a Biden administration agenda on chemicals policy might include.

To help shed some light on these questions, in this week's special US election podcast, Chemical Watch North America managing editor Terry Hyland is joined by a trio of experts who have experience within the EPA, the industry it regulates and the environmental community.

They include Robert Sussman of Sussman & Associates and counsel for the NGO Safer Chemicals, Healthy Families. Mr Sussman also served as deputy EPA administrator under President Clinton and as senior policy counsel to the EPA administrator under President Obama.

Terry is also joined by Erik Baptist, partner with Wiley Rein, former deputy assistant administrator for law and policy in the EPA's Office of Chemical Safety and Pollution Prevention and former senior deputy general counsel in the Office of General Counsel at the EPA.

Also joining the podcast today is Jeff Morris of Morris Solutions, a former director of the EPA's Office of Pollution Prevention and Toxics.

Biden's EPA Expected to Pass Limits on Some 'Forever Chemicals'
Pat Rizzuto, Bloomberg Law
https://news.bloomberglaw.com/environment-and-energy/bidens-epa-expected-to-pass-limits-on-some-forever-chemicals

- Federal water, remediation standards expected
- Limits likely for chemicals beyond PFOS, PFOA

The EPA under a future Biden administration is expected to quickly move to set regulations on "forever chemicals" in water and other areas, but not to restrict the entire group of thousands of the substances, attorneys said in recent interviews.

The Environmental Protection Agency is already expected to set national drinking water limits for two of these chemicals, perfluorooctane sulfonate, or PFOS, and perfluorooctanoic acid, or PFOA, said Cynthia AM Stroman, a partner in King & Spalding LLP's Washington, D.C. office.

President-elect Joe Biden's EPA would be expected to set standards for both of those chemicals and possibly other per- and polyfluoroalkyl substances, or PFAS, that states and federal agencies are finding in drinking water, she said.

The incoming administration also could set waste remediation and other limits for some PFAS, said Lynn Bergeson, managing partner of Bergeson & Campbell P.C., which specializes in chemical policies.

Yet as a centrist, Biden is likely to rely on scientific information and insights into how medical and other high-value industries use some of these chemicals in order to determine a strategy for many of the substances, she said, voicing a perspective shared in interviews with three other chemical policy analysts.

Many Industries Use PFAS
There are thousands of PFAS, of which at least 600 are known to be used in the U.S. by the aerospace, automotive, and various industrial sectors to make products as varied as semiconductor chips, cables, food packaging, and medical stents that keep patients' blood flowing.

But PFAS are an emerging concern across the country because some, such as PFOA and PFOS, have migrated into the soil, water, and air during decades of production and use.

While PFOA and PFOS are no longer made in the U.S., sunlight, weather, and microbes don't break them and similar PFAS down. That means they persist in the environment and can get into water, crops, and farm animals. Exposed people may have weaker immune systems, increased risk of cancer, and other health problems, according to the Centers for Disease Control and Prevention.

Control, Data Gathering Actions
The EPA could quickly take several actions to control PFAS and get more information about them, according to Eve Gartner, managing attorney for the Toxic Exposure and Health Program at Earthjustice, a nonprofit legal law organization.

These include requiring factories seeking Clean Water Act permits to disclose the PFAS they release and their volume; stopping approvals of new PFAS; removing a "loophole" in a regulation that requires environmental releases of certain PFAS to be reported, in order to increase the information the EPA receives; and barring PFAS incineration, pending information on its impacts.

Meanwhile, the EPA's research office is conducting its own research and funding academic research on a range of monitoring, disposal, and toxicity questions surrounding PFAS.

The office is also preparing analyses of five specific PFAS: perfluorononanoate (PFNA), perfluorobutyrate (PFBA), perfluorohexanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), and perfluorodecanoate (PFDA).

Those analyses, scheduled for release for public comment and scientific review next year, are examining the hazards of these chemicals, and what amount of them could be harmful. They could help the EPA move beyond PFOA and PFOS, the two most well-studied of the bunch, to consider limits on others in the family of chemicals.

The EPA's chemical, water, and other regulatory programs typically use the research office's conclusions as they decide whether a chemical should be restricted and, if so, the stringency of controls that would protect people's health.

Biden to Emphasize Chemicals Concerns of 'Frontline' Communities
Pat Rizzuto, Bloomberg Law
https://news.bloomberglaw.com/environment-and-energy/biden-to-emphasize-chemicals-concerns-of-frontline-communities?usertype=External&bwid=00000175-9a6e-dba3-a1fd-dffe5fce0001&qid=7008813&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve_nl%3A2&source=newsletter&item=read-button&region=featured-story&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzUtOWE2ZS1kYmEzLWExZmQtZGZmZTVmY2UwMDAxIiwic2lnIjoiUFI4c1QrL0E3Y2VrL2NML0U3b1J4Nlgyd0lVPSIsInRpbWUiOiIxNjA1MDA5NzYxIiwidXVpZCI6IlZuQTRvMTJ3M1RKeVpIemN5bTBlbmc9PTFlc2hPaS9VMzdyVmh2YWhsaDVyUUE9PSIsInYiOiIxIn0%3D

- EPA likely to look at more chemical hazards, exposures
- Environmental justice to be priority for new administration

President-elect Joe Biden's administration will pay more attention than the Trump administration to the concerns of people with higher-than-average chemical exposures as it decides whether those chemicals should be regulated, attorneys said.

In last month's final presidential debate, Biden described the health fears faced by "frontline" communities—generally those in poor areas with a predominantly minority population that live near oil refineries and chemical manufacturers.

"It matters how you keep them safe," he said. "You impose restrictions on the pollution."

Incorporating concerns of highly exposed and susceptible people into risk evaluations, which determine whether a chemical must be regulated, is part of a broader, significant shift that five attorneys specializing in chemical policies expect from Biden's Environmental Protection Agency.

His EPA likely will examine more ways both people and wildlife are exposed to chemicals and more ways chemicals can harm them, the attorneys said. The more scenarios the EPA examines, the greater chance that more uses of chemicals could be restricted or some could be banned.

Environmental Justice Concerns

Biden has signaled his desire to improve conditions in such places as Louisiana's St. James Parish, which his campaign noted has seven of the ten U.S. Census tracts with the highest cancer risk due to "stunning rates of pollution."

The president-elect also has cited the Route 9 corridor in his home state of Delaware, where residents and politicians have alleged increased illness risks because of ethylene oxide pollution.

Biden said in his environmental justice proposal that he would direct the EPA to create a community notification program requiring industries producing hazardous and toxic chemicals to engage with communities on chemical releases and remediation efforts. The proposal is modeled after a bill (H.R. 6527) that Rep. Lisa Blunt Rochester (D-Del.) introduced in April.

It's unclear how that proposal would work with the existing Emergency Planning and Community Right-to-Know Act (EPCRA), which is intended to inform local communities about hazardous chemicals that nearly industries use to prepare for chemical emergencies.

Attorneys differed on possible near-term chemical actions under Biden's administration.

Biden's EPA could act quickly and revive three rules that Obama's EPA proposed, said Lawrence E. Culleen, a partner in Arnold & Porter Kaye Scholer LLP's Washington office. He referred to two proposed rules (RIN: 2070-AK03; RIN: 2070-AK11) to restrict uses of a solvent called trichloroethylene (TCE), and a third proposal (RIN: 2070-AK46) to restrict another solvent, n-methylpyrrolidone (NMP).

A special section of the 2016 Toxic Substances Control Act amendments authorized the rules, which were proposed in the waning days of the Obama administration. They were shelved soon after President Donald Trump was elected, but they were never withdrawn.

Revising Risk Evaluations

Two attorneys focused on ways Biden's EPA may proceed with the first 10 chemicals it's been evaluating under amended TSCA.

The agency has concluded that four out of the first 10 chemicals pose unreasonable risks. And it proposed the same conclusions for the six remaining substances. Chemicals posing unreasonable risks must be regulated under TSCA.

Since the EPA has found or proposed to find that all 10 chemicals pose unreasonable risks, Biden's EPA won't likely increase the number of those chemicals the EPA will regulate, said Cynthia AM Stroman, a partner in King & Spalding LLP's Washington, D.C. office.

But Biden's broader risk analysis approach could affect the next group of chemicals the EPA is examining, she said. The agency has begun to examine 23 more chemicals' risks.

Yet Biden's EPA may revise some or all of the first 10 risk evaluations or supplement them with additional analyses, according to Steve Owens, a partner with Squire Patton Boggs LLP's Washington and Phoenix, Ariz. offices.

Precedent exists for such a move, said Owens, who oversaw the EPA's chemical and pesticide offices under President Barack Obama. The EPA already plans to do a supplemental analysis of discontinued asbestos uses.

The EPA's move came because the U.S. Court of Appeals for the Ninth Circuit ruled last November that the agency violated TSCA with a policy that automatically disregarded old uses of chemicals even when those discontinued uses could expose people to the chemicals.

Since that ruling, environmental, health, and labor organizations have filed lawsuits challenging some final conclusions about two of the 10 chemicals the EPA has analyzed: a solvent, methylene chloride and three flame retardants, hexabromocyclodecanes (HBCD).

The EPA identified unreasonable risks for both chemicals, but it also identified uses that don't warrant regulation. The agency did that by ignoring chemical exposures TSCA requires it to examine, the groups said. The resulting yet-to-be-developed regulations won't protect people or the environment, they maintain.

The Biden administration's decisions about the first 10 chemical risk evaluations—and court rulings about challenged risk conclusions—will shape the EPA's regulations of the substances and its future chemical analyses.

More Resources Needed
Whatever decisions the EPA makes, its chemicals office needs more resources and staff as evidenced by deadlines the office has missed in releasing the first 10 chemical risk evaluations, several attorneys said.

The evaluations were due, at the latest, by June. The EPA didn't immediately respond to a question about how many staff the office has. A proposed rule revising TSCA fees is under review by the White House.

Increasing the fees that chemical manufacturers pay would "ensure that EPA has the resources needed to conduct robust and comprehensive risk evaluations," said Eve Gartner, managing attorney for the Toxic Exposure and Health Program at Earthjustice, a nonprofit legal law organization.

1,4-Dioxane: Another forever chemical plagues drinking-water utilities
Cheryl Hogue, Chemical & Engineering News
https://cen.acs.org/environment/pollution/14-Dioxane-Another-forever-chemical/98/i43?utm_source=Staff&utm_medium=Social&utm_campaign=CEN

1,4-Dioxane gets around.

It's on laboratory shelves, a reagent familiar to bench scientists. Some drugmakers use it to purify pharmaceutical ingredients. Filter makers employ it to create tiny pores in membranes. The chemical's commercial heyday was in the second half of the 20th century, when it stabilized chlorinated solvents used for metal degreasing.

Since then, the chemical's reputation has dimmed.

In toxicity studies, laboratory rodents given 1,4-dioxane in their drinking water developed liver cancer. The US National Toxicology Program classifies the synthetic compound as "reasonably anticipated to be a human carcinogen." Likewise, the US Environmental Protection Agency deems this synthetic chemical a likely carcinogen. In addition, 1,4-dioxane doesn't readily biodegrade in the environment, the EPA says.

Consequently, production of the compound has dropped, at least in the US. BASF, the last US manufacturer of 1,4-dioxane, halted production at a plant in Louisiana in 2018 and closed the facility a year later, the company tells C&EN in a statement. BASF, however, still imports it from Germany to supply its US customers, and other companies could do similarly.

But even as use of 1,4-dioxane declines, it's not truly going away. The consequence of legacy and ongoing uses—plus the compound's tendency to appear as an impurity in consumer and commercial products—is that 1,4-dioxane is more widespread as a contaminant in drinking water than most other synthetic chemicals, says Thomas K. G. Mohr, author of a technical book about investigating and remediating 1,4-dioxane pollution. Water monitoring data collected in 2010–15 show that more than 7 million people in the US across 27 states had utility-supplied tap water that had detectable 1,4-dioxane, according to the Environmental Working Group (EWG), an advocacy organization.

The problem of 1,4-dioxane pollution isn't unique to the US. However, the US situation reveals a number of regulatory barriers. There is no federal limit on 1,4-dioxane in drinking water. And getting it out of water is challenging.

Chemical conundrum

1,4-Dioxane, a cyclic ether first reported synthesized in 1863 (Ann. Chim. Phys. 1863, 67, 257; Ann. Chim. Phys. 1863, 69, 317), poses a cancer risk when it's released to the air and people breathe it, but the chemical doesn't stick around in outdoor air. It degrades quickly in the atmosphere, with a half-life of less than 5 h, according to the EPA. The compound reacts with photochemically produced hydroxyl radicals to form breakdown products such as aldehydes and ketones. As the US Clean Air Act requires, the EPA regulates 1,4-dioxane as part of a family of substances classified as hazardous air pollutants.

But in water, it dissolves completely, even at high concentrations. It also does not evaporate readily. These properties make 1,4-dioxane difficult to remove from water.

For example, polluted groundwater is commonly treated with pump-and-treat systems in which water is drawn from the ground, aerated or filtered through granulated activated carbon to excise chlorinated solvents and other contaminants, and returned to the aquifer. But this technology doesn't work effectively on 1,4-dioxane.

An expensive, energy-intensive treatment called advanced oxidation processes does the job, though only a few water utilities have it. The technology combines ultraviolet light, which photolyzes organic compounds, with hydrogen peroxide, an oxidant. A study published earlier this year suggests that using hypochlorous acid instead of H2O2 makes this process even more efficient at ridding water of 1,4-dioxane (Environ. Sci.: Water Res. Technol. 2020, DOI: 10.1039/D0EW00316F).

Groundwater infiltrator

Many communities that depend on wells for public drinking water have aquifers tainted with worrisome levels of 1,4-dioxane. This contamination arose from past unregulated industrial practices, in which spent or unwanted solvents were legally dumped into unlined ponds or leaked from underground storage tanks. Some 1,4-dioxane leached out of landfills. In any case, 1,4-dioxane infiltrated aquifers.

Some areas in particular face serious challenges from high levels of contamination. In New York, for example, 1,4-dioxane taints public wells across much of Long Island. It came from manufacturing operations that used the solvent 1,1,1-trichloroethane stabilized with 1,4-dioxane from the 1950s through the mid-1990s, according to water commissioners there. Spills and the unregulated past practice of direct disposal of solvents to the ground led to the pollution. Water districts on Long Island are adopting newer technology to remove the chemical from tap water.

The situation near Ann Arbor, Michigan, is somewhat different. Between 1966 and 1986, 1,4-dioxane filtered into groundwater from lagoons that held wastewater from the manufacture of medical and industrial filtration equipment at Gelman Sciences, now defunct. An underground plume of 1,4-dioxane is headed toward the Huron River, the main source of drinking water for Ann Arbor. A successor company to Gelman, Pall Life Sciences, is treating the tainted groundwater.

Both Long Island and the Ann Arbor area have similar geological formations—both are situated on glacial outwash plains, Mohr says. In this type of substrate, pollutants released to the soil "move every which way fast," he says.

Plumes of 1,4-dioxane from former industrial operations also taint groundwater in arid Southern California. Some water suppliers have shut down wells or blended water from different wells to dilute 1,4-dioxane concentrations.

In other locations, utilities are just as worried about the presence of 1,4-dioxane in sewage. Many cleaning products, laundry detergents, and shampoos, for example, include 1,4-dioxane as an unintentional impurity from surfactants, which are key ingredients in such products that get rinsed down the drain. Although the amounts are small in individual products, they add up when multiplied by many households and commercial establishments such as car washes and hospital laundries.

For utilities that recharge aquifers by injecting treated wastewater underground or discharging it into infiltration basins, all that 1,4-dioxane coming from drains presents a problem. Sewage treatment plants are engineered to reduce biomass and eliminate pathogens from wastewater—not to remove hydrophilic compounds like 1,4-dioxane, Mohr says. Sewage plants remove less than 3% of 1,4-dioxane from the wastewater they treat, the EPA says in a 2019 draft assessment of the chemical.

To prevent contamination of aquifers that get recharged, the California State Water Resources Control Board requires that recycled water contain no more than 1 µg/L of 1,4-dioxane. California utilities that recharge aquifers treat wastewater with reverse osmosis and advanced oxidation processes.

Water releases

The top four US dischargers of 1,4-dioxane into rivers or public sewage systems in 2019 were from pharmaceutical and plastics plants, according to data filed with the Environmental Protection Agency.

Albany Molecular Research Inc. (AMRI)
- Pharmaceuticals
- Rensselaer, New York
- 23,378 kg
- To sewage system, then the Hudson River

Indorama Ventures
- Plastics
- Decatur, Alabama
- 10,453 kg
- To sewage system, then the Tennessee River

APG Polytech, a subsidiary of Taiwan-based Far Eastern New Century
- Plastics
- Apple Grove, West Virginia
- 8,922 kg
- To the Ohio River

DAK Americas, a subsidiary of Mexico-based Alpek
- Plastics
- Moncks Corner, South Carolina
- 8,057 kg
- To the Cooper River

Source: US EPA Toxics Release Inventory, 2019.

Note: The largest environmental release of 1,4-dioxane in 2019 was reported from Huntsman International's Houston plant. This facility sent 197,713 kg of 1,4-dioxane for disposal in an underground injection well.

1,4-Dioxane can be a problem in rivers as well as groundwater. Utilities typically send treated wastewater into rivers, and a handful of US industrial plants still flush the chemical down the drain.

It's unclear how many industrial sites have wastewater permits from a state or the EPA that include a limit on their 1,4-dioxane discharges. Some wastewater permits do specify limits on the chemical, says Heather Barbare of the 1,4-dioxane team of the Interstate Technology and Regulatory Council (ITRC), a group of state regulators. She points to the EPA's Toxics Release Inventory (TRI), which provides information about facilities with the largest discharges.

TRI data for 2019 show that five facilities collectively discharged tens of thousands of kilograms of this chemical into rivers or local sewage systems. Four are facilities that manufacture poly(ethylene terephthalate) (PET)—the clear plastic of beverage bottles—or other polyesters, producing 1,4-dioxane as a by-product. The fifth is a drug ingredient maker.

In most US watersheds, consumers' and industry's legally discharged 1,4-dioxane gets diluted to levels that aren't of health concern to downstream communities' drinking water, Mohr and Detlef Knappe, a North Carolina State University engineering professor, tell C&EN.

But that's not true for North Carolina's Cape Fear River. The river, which flows into the Atlantic Ocean near the city of Wilmington, provides drinking water to more than a million people, according to the EWG.

Knappe says discharges of about 23 kg per day of 1,4-dioxane into the Cape Fear River watershed lead to worrisome levels of the chemical in drinking water drawn downstream, which also includes a stew of per- and polyfluoroalkyl substances (PFAS). The river empties at about 282 m3/s. This is small compared with other US rivers, such as the Tennessee River's output of 1,925 m3/s, meaning that the Cape Fear can't dilute 1,4-dioxane discharges as much as other waterways.

A 2016 study showed that three wastewater treatment plants contributed almost all the 1,4-dioxane found in the watershed, says Knappe, who has studied persistent synthetic chemicals in the Cape Fear River. Those facilities treat wastewater from a variety of industries, including a PET manufacturing plant in Fayetteville and an industrial waste handler in Greensboro, he says. Levels of 1,4-dioxane in the Cape Fear River have dropped since 2014 when Knappe alerted North Carolina officials to the contamination. He says the drop is probably due to a decrease in industrial discharges of the chemical.

Knappe sees a tension between upstream sewage treatment plants that can't easily remove 1,4-dioxane that is legally discharged and downstream utilities that want to keep the potential carcinogen out of drinking water. Neither wants to resort to expensive advanced oxidation processes to remove the chemical.

Regulatory hodgepodge

There's no federal limit on 1,4-dioxane in tap water. The EPA has a nonbinding health advisory level for 1,4-dioxane in drinking water of between 0.35 and 35 µg/L. The numbers correspond, respectively, to a lifetime cancer risk of 1 in a million and 1 in 10,000. The World Health Organization, meanwhile, has a suggested threshold of 50 µg/L.

The EPA is taking a detailed look at risks from 1,4-dioxane under the federal chemical control law, the Toxic Substances Control Act. In its 2019 draft version of that assessment, which the agency is expected to finalize by the end of 2020, the EPA determined that the chemical may pose an unreasonable risk to some workers. If finalized, this finding could lead to regulation, but the EPA may refer the issue to the Occupational Safety and Health Administration.

But the EPA chose not to address in the assessment the general public's exposure to the chemical in drinking water. The EPA says in a fact sheet it can "adequately assess and effectively manage risks from 1,4-dioxane" to the general public using other federal statutes, including the Safe Drinking Water Act (SDWA). Such regulation would take years to implement.

" 1,4-dioxane is more widespread a contaminant in drinking water than most other synthetic chemicals." ---Thomas K. G. Mohr, author of a book on investigating and remediating 1,4-dioxane pollution

In the meantime, a number of states are working to address 1,4-dioxane contamination in drinking water. Those actions are all over the map, according to data compiled by the ITRC. A handful of states have enforceable limits on the chemical in drinking water. Others have legal cleanup levels for aquifers. Some adopted the EPA's advisory levels, while some have no numeric standards.

New York, with a large affected population living on Long Island, has taken the biggest regulatory action. In July, the state adopted the first enforceable limit for 1,4-dioxane in drinking water in the US, setting it at 1 µg/L. New York requires all public water systems, regardless of size, to test and monitor for the compound. Last year, the state enacted a law intended to keep more 1,4-dioxane from entering its drinking-water supplies by restricting levels of 1,4-dioxane in cosmetics and personal care and cleaning products. Companies that make those products, in response, are changing their manufacturing processes to eliminate the formation of 1,4-dioxane.

Some other states are following New York's lead. In September, New Jersey's Drinking Water Quality Institute recommended the state adopt an enforceable maximum contaminant level for 1,4-dioxane of 0.33 µg/L. The institute—a panel of academics, environmental health specialists, and public water utility representatives—endorsed the use of advanced oxidation processes to remove the contaminant from drinking water.

California, too, has begun steps toward restricting 1,4-dioxane in consumer goods and setting an enforceable limit in drinking water.

This mixture of state actions and their varying numeric levels is confusing, says Tasha Stoiber, senior scientist at the EWG. She and other environmental and health advocates want the EPA to set an enforceable federal drinking-water standard for 1,4-dioxane and are urging utilities to test their drinking water regularly for the presence of the chemical.

But the multiyear process that the EPA must go through to regulate contaminants under the SDWA makes a federal standard for 1,4-dioxane unlikely in the short term. Since Congress revised the process in 1996, the EPA hasn't regulated any contaminants—except for those ordered by Congress—in drinking water. Earlier this year, the EPA opted not to set a drinking-water limit for perchlorate, an ingredient in rocket fuel that interferes with thyroid functioning, saying state regulation of the compound sufficiently protects public health. This could prove a precedent for 1,4-dioxane, Mohr says.

Regardless of whether the EPA or states set limits, Stoiber contends, it's easier and less expensive to stop environmental releases of 1,4-dioxane than it is to treat drinking water to get it out.

Biden plans PFAS rules, hazardous designation

E. A. Crunden, E&E News

https://www.eenews.net/greenwire/2020/11/10/stories/1063718173?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

President-elect Joe Biden is planning to "tackle" toxic forever chemicals by setting enforceable drinking water limits, designating the substances as hazardous and finding PFAS substitutes for consumer items.

The former vice president included actions to address per- and polyfluoroalkyl substances, or PFAS, in his environmental justice plan, and environmental groups now hope the issue will stay top of mind when he takes office in January 2021.

The plan mentions PFAS in a section on water pollution, presenting the president-elect's approach as "comprehensive" and centering on regulatory standards for drinking water, among other actions.

"Instead of making empty promises with no follow-through, Biden will tackle PFAS pollution by designating PFAS as a hazardous substance, setting enforceable limits for PFAS in the Safe Drinking Water Act, prioritizing substitutes through procurement, and accelerating toxicity studies and research on PFAS," the plan states.

Under President Trump, EPA touted its PFAS Action Plan and the agency's broader work on addressing contamination by the family of thousands of chemicals, which have been linked to cancer and other severe health issues. But critics say EPA has stalled on actions like setting a maximum contaminant level (MCL) for PFAS.

Organizations closely scrutinizing PFAS, like the Environmental Working Group, are sounding an upbeat note on how a Biden administration might approach the chemicals.

Scott Faber, senior vice president for government affairs at EWG, highlighted the plan's emphasis on both setting limits in drinking water through an MCL and the prospect of designating PFAS as hazardous substances under the federal Superfund law.

EPA currently has health advisories in place for two PFAS — PFOA and PFOS — of 70 parts per trillion in drinking water, but that threshold is not enforceable. No PFAS are designated as hazardous substances at present by EPA.

If that designation changes and the chemicals come under Superfund law, it would spark a cleanup process at sites singled out by the agency.

"There's nothing stopping a Biden-Harris administration from designating PFOA and PFOS as hazardous substances on day one, and they should," Faber said.

Biden's plan also aims to seek PFAS substitutions for various products available in the marketplace. A number of everyday items contain PFAS, including dental floss, nonstick pans and rain jackets.

One target of regulations could be food packaging. The presence of the chemicals in such items raises the likelihood of human consumption. As PFAS have bioaccumulative properties, ingesting them poses a health risk.

Food packaging has also brought PFAS into composting facilities in various cities, like Ann Arbor, Mich., and concerns about the issue are leading to an uptick in legislation and regulations across multiple areas.

Two states, Maine and Washington, have already passed legislation that would ban PFAS in food packaging once a suitable alternative can be identified. San Francisco has also barred PFAS in food packaging. Rep. Debbie Dingell (D-Mich.) previously introduced legislation (H.R. 2827) at the federal level that would ban PFAS in food containers, but that bill has not seen any action.

Including substitutes to PFAS-laden products "really shows the Biden-Harris team understands that it's not just our drinking water that is a source of PFAS pollution," Faber said.

Industrial discharges of PFAS have been a major concern for environmental and health groups, something that could be addressed through the Clean Water Act and Clean Air Act.

The Biden campaign did not respond to a request for comment about the president-elect's PFAS plan.

Bracing For Stricter TSCA, Chemical Industry Vows Cooperation With Biden
Rick Weber, Inside TSCA
https://insideepa.com/tsca-news/bracing-stricter-tsca-chemical-industry-vows-cooperation-biden

Chemical industry groups are pledging to work with President-elect Joe Biden, citing a worsening COVID-19 pandemic and a struggling economy as the basis for collaboration on a common agenda even while industry lawyers anticipate tougher chemical risk reviews and TSCA regulations that could slow approval for new products.

"You enter office at a uniquely precarious time in our history, one that at its outset will require rebuilding the fragile economy, managing through the COVID-19 pandemic, and uniting and healing a bitterly divided people," chemical industry leaders said in a Nov. 7 letter to Biden and Vice President-elect Kamala Harris.

"As an industry built on innovation and a key driver of environmental progress and sustainability, we see change not as a threat but as an opportunity," says the letter, which was sent by the American Chemistry Council (ACC) and signed by ACC CEO and President Chris Jahn and ACC executive committee members.

"We will commit to always being a constructive voice at the table providing our expertise so that we may rebuild our country together," adds the letter, which was sent shortly after the presidential race was called for Biden.

The industry request for a seat at the table comes as the Biden administration is preparing to enter office at a critical time for implementation of the 2016 reforms to the Toxic Substances Control Act (TSCA).

The Trump EPA is poised to issue six of the remaining first 10 chemical risk evaluations mandated by the revised TSCA, assessments that will set the basis for first-time risk-mitigation rules. The agency is also slated to issue final regulations governing five persistent, bioaccumulative and toxic (PBT) substances.

But environmentalists are pressing the incoming Biden administration to strengthen its scrutiny of chemicals. For example, a group of former EPA officials has called on the next administration to quickly tighten the agency's risk evaluation methods under TSCA, re-do the first 10 evaluations and regulate some "immediate" risks even while new evaluations are being finalized.

Anticipating that a Biden EPA will adopt such approaches, other chemical industry groups are also pledging to work with a Biden administration while also highlighting the role the industry could help play in addressing the pandemic.

In a Nov. 7 statement, the Society of Chemical Manufacturers and Affiliates (SOCMA) pledged to work with an incoming Biden administration on "key issues vital to the success" of the industry while addressing the COVID-19 pandemic.

"With an expectation of greater federal oversight, SOCMA will provide an impact assessment from the election and is poised to begin establishing relationships with newly appointed staff, reinforcing connections with longtime allies, and focusing on key priorities that could impact the growth of the industry," said SOCMA in a Nov. 7 statement.

"The extraordinary events of 2020 and the COVID-19 pandemic have significantly altered life as we know it. SOCMA welcomes the opportunity to highlight the important role specialty chemical manufacturers play in the U.S. recovery with President-elect Biden and other newly elected leaders," said SOCMA President and CEO Jennifer Abril.

TSCA Priorities

While industry groups brace for stepped-up EPA oversight, some industry attorneys are warning that the incoming Biden administration could strengthen the current TSCA program.

For example, the law firm Arnold and Porter issued a post-election analysis that suggests environmentalists' calls to expand the scope of EPA risk evaluations could gain traction with the incoming administration.

"President-elect Biden could change some aspects of the rules implementing the 2016 amendments to TSCA that have proven to be the most controversial and subject to challenge by environmental groups, such as provisions governing the conditions of use the EPA will consider during risk evaluations of existing chemicals," says the analysis.

The analysis also identifies end-of-year policy goals for the Trump administration that could be halted for review and revision by an incoming Biden administration.

"The EPA also could reconsider the Trump Administration's risk management rules for [PBT] Substances, which, per statute, must be finalized by the end of 2020," according to the Arnold and Porter analysis of a potential Biden agenda.

The Arnold and Porter analysis also anticipates stricter oversight of new chemicals, an issue where the Trump administration has touted its success in meeting a 90-day review deadline but which environmentalists have criticized as undercutting thorough risk reviews and jeopardizing public health.

"Compared to the relatively rapid pace of approval of new chemicals over the past few years, new EPA leadership likely will implement more aggressive review procedures, leading to lengthier approval processes for new chemicals," the firm warns.

"For example, the EPA could revert to practices under the Obama Administration in 2016, including placing additional restrictions on uses of new chemicals when approving them for market entry in the U.S. and requiring manufacturers to generate new health and environmental effects studies for existing chemicals undergoing EPA reviews," the law firm analysis states.

Eric Baptist, a former top EPA lawyer on TSCA issues who is now a partner at the Wiley Rein law firm, also expects EPA will step up scrutiny of new chemicals and expand the scope of its evaluations of existing chemicals.

According to an article posted on his firm's website, he said he expects a Biden administration to review conditions of use of existing chemicals even if they are already regulated by other EPA programs -- an approach the Trump EPA has avoided.

He also said he expects a change in the agency's evaluations of pre-manufacture notices (PMNs) as the agency is seeking to reject requests for PMN approvals that officials believe are insufficient in their current form.

"The EPA would like more flexibility to reject or force submissions to the back of the line if they fail to meet the needed requirements," Baptist wrote in the Nov. 2 blog post. He added that if the agency could reject submissions that do not meet basic requirements, it could help the agency meet the 90-day review deadline as the review clock is paused in such a case.

Environmental Justice

The Arnold and Porter analysis also stresses the importance of addressing climate change as a guiding principle for an incoming Biden administration, while including a section on environmental justice with Vice President-elect Harris expected to play a central role on both issues.

"One of the highest priorities of the Democratic environmental platform is to address the disproportionate impacts of environmental and public health stressors on communities of color and low income communities," says the law firm analysis, citing legislation introduced by Harris as an example of her "expertise" on the issue.

The analysis notes that during the campaign, Biden committed to adopting a series of measures to strengthen federal consideration of environmental justice, including strengthening President Bill Clinton's Executive Order 12898, which focuses federal attention on addressing environmental justice and the disproportionately high and adverse human health or environmental effects of agency programs in "minority populations and low-income populations"; establishing new interagency leadership structures to elevate environmental justice issues throughout the federal government; establishing a new Environmental and Climate Justice Division at the Department of Justice; and targeting 40 percent of the investments in clean energy to disadvantaged communities.

"The incoming administration will need to pursue these objectives through existing authority through various agencies, since prospects for Senate passage of comprehensive environmental justice legislation are low," the analysis notes.

Yet the U.S. Chamber of Commerce in a Nov. 9 call with reporters touted the prospects for bipartisan legislation under a Biden administration emphasizing another COVID-19 relief package and infrastructure spending -- including for climate change resiliency -- despite a closely divided Senate.

U.S. Chamber Chief Policy Officer Neil Bradley offered an agenda that runs counter to "what common wisdom dictates" -- that major legislation will not get passed by an incoming Biden administration and an even more partisan, divided Congress. He pledged the business group to finding "items that we can agree on" in working with the new administration while noting "there will be plenty" of differences.

Senate control appears likely to stay in the hands of Republicans, with races in North Carolina and Alaska too close to call at press time, while two Georgia runoff elections on Jan. 5 could give Democrats at best 50 seats with Vice

President-elect Harris breaking the tie and shifting partisan control of the chamber. -- Rick Weber (rweber@iwpnews.com)

After Biden Win, Environmentalists Push To Implement PFAS Pledges

Diana DiGangi, Inside TSCA

https://insideepa.com/tsca-news/after-biden-win-environmentalists-push-implement-pfas-pledges

Environmentalists are pressuring President-elect Joe Biden to implement pledges that he and his running-mate, Vice President-elect Kamala Harris, made to phase out non-essential uses of per- and polyfluoroalkyl substances (PFAS) and impose strict regulatory requirements on their releases.

In a Nov. 9 statement, the Environmental Working Group (EWG) touted elements in Biden's environmental justice plan, in which the former vice president vowed to use the federal government's purchasing power to phase out various uses of PFAS.

Citing a series of commitments Biden has made to address the class of chemicals, the group noted that "the president-elect also pledged to prioritize PFAS substitutes in the marketplace," and urged him to require regulators to take steps to phase them out.

"That means Biden could direct the EPA and the [Food & Drug Administration (FDA)] to quickly phase out non-essential uses of PFAS in food packaging, cosmetics, sunscreens and other everyday products," the group said.

Their calls appear to go beyond the commitments that Biden made during the campaign. For example, according to his environmental justice plan, Biden promised to prioritize PFAS "substitutes through procurement."

The commitment was part of a section of the plan devoted to improving drinking water quality, and included a series of regulatory steps that the Trump EPA has considered but not yet acted on, including designating the chemicals as "hazardous substances" under the Superfund law, setting enforceable standards under the Safe Drinking Water Act and accelerating toxicity studies and research on PFAS.

EWG and other environmentalists have long pressed the Trump administration to adopt such measures but officials have been slow to act. For example, while EPA has drafted a plan to list certain PFAS under the Superfund law, the measure has stalled amid opposition from the Defense Department (DOD), whose officials fear it would significantly increase its cleanup liability.

But industry attorneys have long warned that a Biden administration is expected to act more quickly than the Trump administration. Jim Barnette, a former House GOP staffer who now represents industry clients, told Inside TSCA that trade associations and individual companies in the PFAS supply chain should brace for a Biden win.

Scott Faber, EWG's senior vice president for government affairs, noted in the group's statement that Biden's commitments to regulate releases of the chemicals, such as setting a drinking water standard, "would have a huge impact on public health."

Designating PFAS as hazardous substances under Superfund would also be historic, Faber writes, but Biden's pledge to prioritize PFAS substitutes could be important as it would kick-start phaseouts of non-essential uses, and begin to cycle many of the "forever chemicals" out of the supply chain.

"There are no federal limits on PFAS releases and uses and no requirements to clean up PFAS pollution," the group says.

Other environmental groups have also pushed Biden to clamp down on the chemicals. For example, Safer States, a group that advocates for stricter chemical regulatory policies, issued a broad agenda for the next president to address PFAS, including immediately barring EPA from approving new PFAS uses under the Toxic Substances Control Act (TSCA) while the agency works to prohibit "non-essential" uses.

Congressional Action

While environmentalists are generally pressing the incoming Biden administration to address PFAS, many expect that Congress will continue to be interested in addressing the issue.

EWG legislative attorney Melanie Benesh recently called the amount of interest in PFAS in the 116th Congress "unprecedented," adding that she expects the issue to continue to gain attention next year.

But Barnette says that if Congress is unable to agree on legislative provisions, such as bipartisan amendments House lawmakers are seeking to add to pending defense authorization legislation, a Biden administration could still implement them "administratively."

For example, EWG's Faber adds that while Congress has already directed DOD to phase out uses of firefighting foam by 2024, the incoming administration could "direct [DOD] to accelerate efforts to end the use of PFAS-based firefighting foam, impose a moratorium on the incineration of remaining stocks of PFAS foam, and accelerate PFAS cleanup at military installations." -- Diana DiGangi (ddigangi@iwpnews.com)

Environmentalists Fault EPA's Speedy Review For Second PV29 Evaluation
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/environmentalists-fault-epa-s-speedy-review-second-pv29-evaluation

As EPA scrambles to complete the remaining six of its first 10 chemical evaluations under TSCA before the end of the year, environmentalists are criticizing the agency's plan for a speedy peer review of its revised draft evaluation of pigment violet 29 (PV29), charging in part that the truncated process does not allow for adequate analysis.

"[B]ecause it is a letter peer review, it appears there will be no interaction among the panelists, no public meeting, and no report developed; only individual comments from the six individuals," Richard Denison, lead senior scientist with the Environmental Defense Fund (EDF), tells Inside TSCA.

Denison also says that "it is not clear what if any screening" was conducted to determine if the reviewers have any potential conflicts of interest.

And he warns that the rushed approach, unlike reviews conducted by the Science Advisory Committee on Chemicals (SACC), does not ensure the agency will take any criticisms into account.

"This is a far less accountable process than has been the case for the SACC peer reviews conducted to date. No discussion of issues among peer reviewers, no effort to develop a consensus, no ability to hear from members of the public or for the public to hear from the peer reviewers. And less accountability for the agency to pay heed to the scientific advice it receives."

Another environmentalist blames EPA for the rushed process it now faces, a situation that is exacerbated by the scramble the agency faces to complete by the end of the year evaluations for PV29 and the other five chemicals in the first batch of 10 EPA is conducting following Congress' 2016 reform of the Toxic Substances Control Act (TSCA).

In addition to completing the first 10 evaluations by the end of the year, the Trump administration must still complete a suite of regulatory measures that must still face White House review before President-elect Joe Biden is inaugurated Jan. 20.

"Their backs are against the wall; they don't have much time. But it's really their own fault since they plunged ahead with a flawed risk evaluation and then had to back peddle when public commenters and SACC took them to task for lacking basic data on PV29," the second source says.

Asked about the concerns surrounding the letter peer review, an agency spokesperson tells Inside TSCA, "The agency plans to issue final risk evaluations for the remaining 6 of the first 10 chemicals and finalize the [persistent bioaccumulative and toxic (PBT)] rule by the end of 2020."

The environmentalists' comments come in response to the agency's Oct. 29 release of its revised second draft evaluation of PV29, which strengthened the agency's initial findings of the substance's risks.

While the initial draft, released in November 2018, found the substance poses no unreasonable risks, the revised draft found that eleven of 14 uses of the substance -- which is widely used in acrylic and automotive paints, printing inks and packaging -- pose unreasonable risks to humans and are eligible for regulation under section 6 of TSCA.

The initial draft drew widespread criticisms from EPA advisors and environmentalists, in large part because of the limited information the agency has relied on. During their June 2019 review of the PV29 draft evaluation, EPA advisors raised sharp concerns about the quality of the data, with some urging officials to gather more data because the draft does not support its threshold finding.

Additional Data

In response, EPA last February issued its first-ever section 4 test orders since TSCA reform, requiring the two known domestic producers to perform tests to better characterize PV29's solubility and worker inhalation exposure.

"The test order information combined with additional particle size information received from the manufacturers had a significant impact on EPA's analysis of the potential exposure and health effects of PV29. As a result of this updated analysis, the revised draft risk evaluation now shows unreasonable risk for [11] out of 14 conditions of use," the agency says in its Oct. 30 Federal Register notice.

But in the face of the delays in completing the evaluation, which was slated for finalization by June 21, EPA is now proceeding with a letter peer review -- a lower-level peer review than the usual SACC review and is not expected to include a public meeting -- at the same time that the public reviews the new document.

"EPA feels it is important that independent, scientific experts have the opportunity to provide input on this new information and analysis before the risk evaluation is finalized, and EPA will conduct an independent expert peer review in the form of a letter peer review simultaneous to the period of solicitation for public comment," the notice says.

EPA has asked six external experts to conduct the letter peer review, a process wherein the reviewers do not meet and no consensus report is jointly written.

Instead, EPA will receive the individual recommendations of each of the six reviewers, including George Cobb, a professor of environmental chemistry at Baylor University in Texas; Yue-Wern Huang, a toxicology professor at Missouri University of Science and Technology; John Kissel, professor emeritus of environmental and health sciences at the University of Washington; Emily Reinke, a biologist with the U.S. Army Public Health Center; Nikaeta Sadekar, a toxicologist with the Research Institute for Fragrance Materials in New Jersey and Yiliang Zhu, a professor of biostatistics at the University of New Mexico's medical school.

Four of the six served last year as members of the SACC panels that peer reviewed EPA's first 10 draft risk evaluations, including the first PV29 evaluation.

It appears that the panel members were selected by agency staff in the Office of Science Coordination and Policy (OSCP) within EPA's toxics office (OPPT), according to an Oct. 16 memo that the then-acting director of OPPT's risk assessment division sent to OCSP.

Still, it is unclear which members, if any, underwent a conflict of interest screen, as is usually conducted for peer reviewers, an issue of concern for both environmentalists, with Denison describing the peer review as "quite compromised," based on its size, speed and process.

"There are serious concerns with a letter review at this point in the process," the second environmentalist says. "One is EPA's failure to obtain the views of the full SACC, which made numerous recommendations that EPA has not followed and should have a chance to weigh in on the revised evaluation."

"Another is the likelihood that the letter reviewers will not have time to consider public input because the letter review and public comment period will overlap," the environmentalist adds.

Denison considers the process "far too rushed, with only a 30-day period for peer reviewers to read and analyze the voluminous materials and develop their comments. And because the public comment period runs concurrently, peer reviewers will not have any benefit of having public comments to look at."

Charge Questions

According to EPA's charge questions, the agency is asking a series of questions about the new data the manufacturers provided and the inferences EPA makes in the new draft based upon that information. For example, EPA explains that "[h]uman health exposure and hazards from inhalation of particles are associated with both the particle size as well as the concentrations of the particles in the air. Smaller particles are associated with deposition deeper in the lungs, in the alveolar region, than larger particles."

EPA explains that prior to releasing its first draft evaluation, it received particle size information from BASF indicating "median particle size diameter of 46.9 [micrometer (um)]." But the agency says that after it released the draft, Sun Chemical provided "additional particle size distribution (PSD) data . . . describing a median diameter of [PV29] of 0.043 um, or 1000 times smaller than the initially-reported particle size used in the draft risk evaluation." As a result, EPA explains that "risks from inhalation of [PV29] dust were characterized using all reasonably available data to represent this range of potential particle diameters."

EPA also explains that Sun Chemical submitted total dust measurements within six workers' breathing zones during typical activities at its manufacturing facility after the release of the first draft evaluation, resulting in individual exposures of respirable dust ranging from 0.22 to 1.2 milligrams per cubic meter of air (mg/m3). But the study "did not specifically measure [PV29]-containing respirable dust," EPA said, resulting in an order to address uncertainties.

EPA explains that it uses the results of the two studies to estimate "'central tendency' and a 'high-end' exposure concentration of [PV29] in the breathing zone." The agency asks peer reviewers to consider its approach to estimating workers' inhalation exposure and provide recommendations for improvement.

As in earlier TSCA evaluations, EPA used a margin-of-exposure (MOE) approach to assess risk in the draft evaluation, and it asks reviewers to consider this aspect of its evaluation as well, where it combines the particle size data with the breathing zone data. "EPA calculated risk MOEs assuming three different particle sizes (0.043, 10.4, and 46.9 um) . . . Dust particles less than 100 um are considered non-respirable, and smaller particles are understood to have a higher deposition of the particles in the alveolar region of the lung." -- Maria Hegstad (mhegstad@iwpnews.com)

EPA seeks small entity advice on HBCD risk management rule
Inside TSCA
https://insideepa.com/tsca-takes/epa-seeks-small-entity-advice-hbcd-risk-management-rule

EPA is seeking nominations from small entity representatives to serve on a panel that will advise the agency on how to craft its pending TSCA risk management rules to address the unreasonable risks the agency identified in its final evaluation of hexabromocyclododecane (HBCD) and a cyclic aliphatic bromide cluster of flame retardant chemicals.

EPA Nov. 9 called for representatives from groups, including owners or operators of small businesses, small organization officials, or small-government officials to serve on the Small Business Advocacy Review (SBAR) panel it will form, as required by the Regulatory Flexibility Act (RFA).

"The panel will focus on the agency's development of a proposed rule to address unreasonable risks identified in EPA's recently completed Toxic Substances Control Act (TSCA) risk evaluation for HBCD," EPA's Nov. 9 announcement states.

"Under TSCA, EPA is required to evaluate the risks associated with exposure to existing chemicals in commerce using the best available science then take action to reduce or eliminate any unreasonable risks identified. The agency issued a final risk evaluation for HBCD in September 2020 showing unreasonable risks to the environment, workers, and occupational non-users under certain conditions of use. EPA is now moving to the risk management step in the TSCA process by working to draft regulations to protect public health and the environment from the unreasonable risks identified in the final risk evaluation."

But the agency notes on its website that the panel will advise officials on how to craft a rule that does not unduly burden small entities. "The Panel process offers an opportunity for small businesses, small governments, and small not-for-profit organizations (collectively referred to as small entities) to provide advice and recommendations to ensure that EPA carefully considers small entity concerns regarding the impact of the potential rule on their organizations," the agency says on its website.

EPA explains that the RFA requires it to establish an SBAR panel "for rules that may have a significant economic impact on a substantial number of small entities. The SBAR Panel will include federal representatives from the Small Business Administration (SBA), the Office of Management and Budget (OMB), and EPA."

The announcement follows similar calls in September seeking small business representatives to serve on such panels for the first two TSCA risk evaluations EPA has completed, methylene chloride and 1-bromopropane (1-BP).

For HBCD, the pending rules are intended to address the agency's conclusions in its final risk evaluation that six of 12 commercial, industrial, recycling or disposal uses it evaluated pose "unreasonable risks" to workers and the environment that require regulation. Unlike the first two evaluations, EPA strengthened its final evaluation of HBCD from the draft, finding that six of 12 uses pose unreasonable risk -- a change from the draft which found no uses pose such risks.

The chemicals have primarily been used as a flame retardant "added to polystyrene to make insulation boards for buildings" with smaller amounts of HBCD "incorporated into solder paste and replacement automobile parts," EPA staff said during a briefing last month hosted by the SBA Office of Advocacy, where EPA floated regulatory options.

EPA is asking for nominations for the SBAR to be submitted by Nov. 23. Agency staff is also scheduled to host a Nov. 20 public webinar regarding the risk management actions they are beginning to consider for HBCD.

Bayer-Roundup Judge Moves to Resume Cancer Trials in U.S. (2)

Joel Rosenblatt, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/bayer-roundup-judge-moves-to-resume-cancer-trials-in-u-s?usertype=External&bwid=00000175-aed2-d8cc-ab75-aedb2f5a0001&qid=7008813&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve_nl%3A44&source=newsletter&item=headline&region=digest&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzUtYWVkMi1kOGNjLWFiNzUtYWVkYjJmNWEwMDAxIiwic2lnIjoiUWxxZFZiWldhTnA4SzJ0OXR0N3ZvajB3djBJPSIsInRpbWUiOiIxNjA1MDA5NzYxIiwidXVpZCI6IlZuQTRvMTJ3M1RKeVpIemN5bTBlbmc9PTFlc2hPaS9VMzdyVmh2YWhsaDVyUUE9PSIsInYiOiIxIn0%3D

Bayer AG may face as many as four U.S. trials over its Roundup weedkiller next year after a judge said Monday he's ready to resume putting cases in front of jurors.

With thousands of lawsuits alleging the herbicide is cancerous still unresolved even after Bayer announced an $11 billion settlement plan in June, U.S. District Judge Vince Chhabria in San Francisco said it's time to move forward following a period during which all the federal cases were on hold for negotiations.

Read More: Bayer's Costs to Fight Future Roundup Lawsuits Climb

Of the handful of cases that are closest to being ready for trial, Bayer will still have an opportunity to argue for their dismissal or try to get plaintiffs' expert witnesses disqualified. But if the company doesn't get the suits thrown out or settled, it faces a Jan. 25 pretrial conference for the first case.

"I'll get to work on those cases promptly," the judge told lawyers during a hearing, noting that only about half of the approximately 4,000 cases he oversees are subject to settlement agreements.

Bayer said in an emailed statement that due to the pandemic, it doesn't expect month-long trials to happen any time soon. "We remain fully committed to settling the Roundup litigation and are reaching out to counsel for virtually all not yet settled cases," the company said.

Settlements in state and federal courts "are being successfully implemented," Ken Feinberg, the court-appointed mediator for the Roundup litigation, told Chhabria. "We are not there yet but we are making substantial progress."

Bayer lost three Roundup trials in 2018 and 2019 with average awards of almost $50 million per plaintiff that sent its stock into a downward spiral. The legal threat, based on consumer arguments that Roundup caused their cancer, has weighed on Bayer since its 2018 acquisition of Monsanto, the longtime manufacturer of the herbicide. Bayer lost its appeal of the first verdict -- though it did win a reduction in damages -- and is still appealing the second and third verdicts.

Bayer said last week that it has settled or at least reached general agreements for 88,500 claims, but that it can't say with certainty that the total number of existing Roundup suits won't grow beyond 125,000 until the entire settlement process is complete.

If Judge Chhabria moves to resume the next set of cases, "we would expect a negative outcome for Bayer yet again, with juries likely to continue to hand the plaintiffs multimillion dollar awards," said Anna Pavlik, Special Situations Senior Counsel at United First Partners in New York. "Such jury awards would continue to put pressure on Bayer to come up with a more comprehensive settlement offer, which may entail higher per-plaintiff payouts as well as a possible change of the RoundUp label."

The vast majority of the unresolved Roundup suits are in state courts and not subject to Chhabria's deadlines or decisions.

The case is In re Roundup Products Liability Litigation, 16-md-02741, U.S. District Court, Northern District of California (San Francisco).

(Updates with company statement in fifth paragraph.)

--With assistance from Tim Loh.

Bayer makes 'substantial progress' in Roundup cancer lawsuits, mediator says
Jonathan Stempel, Yahoo Finance
https://finance.yahoo.com/news/bayer-makes-substantial-progress-roundup-220556259.html?soc_src=social-sh&soc_trk=tw&tsrc=twtr

(Reuters) - A court-appointed mediator on Monday said Bayer AG has made "substantial progress" toward resolving tens of thousands of remaining claims that its Roundup weedkiller causes cancer.

The mediator Kenneth Feinberg spoke at a Zoom hearing in San Francisco federal court, where a judge still oversees nearly 2,000 unresolved cases over glyphosate-based Roundup, which Bayer acquired with its purchase of Monsanto. Other cases are in state courts.

"We're not there yet but we are certainly making substantial progress," said Feinberg, who oversaw compensation programs for victims of the Sept. 11 attacks and 2010 Gulf of Mexico oil spill. "It's just a question of when and how quickly they'll get resolved."

U.S. District Judge Vince Chhabria had previously paused the federal litigation and given Bayer until Nov. 2 to settle.

Bayer has said 1,861 of the 3,787 plaintiffs in that litigation had not settled. Chhabria did not extend the stay, meaning some cases could move toward trials.

"I'm not interested in having such an elongated schedule for the adjudication of these cases," he said.

Bayer has said Roundup is safe for human use. It said it has resolved about 88,500 of an estimated 125,000 filed and unfiled claims, and is "fully committed" to settling the litigation.

The German company inherited liability for the lawsuits when it bought Monsanto for $63 billion in June 2018, becoming the world's largest supplier of seeds and pesticides. Its shares have since fallen 54%.

In June, Bayer projected it would pay up to $10.9 billion to resolve Roundup litigation, mostly for existing claims and $1.25 billion for future claims.

Last week, it increased the projected cost of future claims to $2 billion, and took a 9.25 billion euro ($10.9 billion) writedown in its crop science business.

Bayer lost three Roundup trials in 2018 and 2019. In October, the California Supreme Court declined to hear its appeal from a $20.5 million award to school groundskeeper Dewayne Johnson for his non-Hodgkin's lymphoma.

The case is In re Roundup Products Liability Litigation, U.S. District Court, Northern District of California, No. 16-md-02741.

(Reporting by Jonathan Stempel in New York; Editing by Bill Berkrot and Stephen Coates)

USDA Suggests Organic Is Overrated, but Not Everyone Agrees
Katherine Martinko, Treehugger
https://www.treehugger.com/usda-organic-overrated-not-everyone-agrees-5086589

The U.S. Department of Agriculture doesn't want you to worry so much about pesticides. The fruits and vegetables that you buy at the store are not as contaminated as you might think, based on the latest annual report from the Pesticide Data Program (PDP). Every year tests are done to detect pesticide residues on food to ensure that levels are not exceeding those set by the U.S. Environmental Protection Agency (EPA).

This year's report tested in 10 states and included nearly 10,000 samples of fresh, frozen, and processed fruits and vegetables. It stated that "nearly 99% of the samples tested had residues below the tolerances established by the EPA, with 42.5% having no detectable residue." This was after samples had been washed under cold running water with no additional cleansers, as a consumer would be likely to do. The conclusion? "This means you can eat with the confidence that your food is safe and nutritious for you and your family."

Well, Maybe Not Quite So Fast...

Treehugger reached out to the Environmental Working Group (EWG), which is well-known for its work on pesticide testing and the resulting Dirty Dozen and Clean Fifteen lists that it releases annually. The EWG's Shoppers Guides are based on the same data gathered by the Pesticide Data Program, and they use more than 43,700 samples taken by the USDA and the Food and Drug Administration (FDA).

Dr. Thomas Galligan, a toxicologist who works with the EWG, weighed in on the USDA's announcement.

"It is important to remember that, when it comes to pesticide levels in produce, 'legal' does not mean safe. Federal food tolerance residue levels often allow for higher exposure levels than public health advocates, including EWG, consider to be safe. Many peer-reviewed scientific studies have found disturbing links between pesticide exposures and human health issues, including cancer, infertility, hormone disruption and harm to children's developing brains. If EPA tolerance levels were set to protect all children especially, as we believe they should be, more fruits and vegetables would fail."

The EPA's pesticide limits are regarded by some to be insufficient to safeguard children's health. Children are more susceptible to the harmful effects of pesticides than adults, and a 1996 Food Quality Protection Act stated that the EPA must apply "an extra margin of safety to legal limits for pesticides in food." When the EWG followed up with an investigation in February 2020, it found that "this tenfold margin of safety was not included in the EPA's allowable limits for almost 90% of the most common pesticides."

One interesting point raised by the Pesticide Data Program report, however, is that fear of pesticide contamination is leading many households to avoid buying fresh produce because they cannot afford organic. Safe Fruits and Veggies reports that "the creation of a 'fear barrier' to consumption further undermines public health efforts to improve diets."

"In fact, 94% of registered dietitians agree that fear-based, inaccurate information about produce safety is negatively impacting their efforts to increase consumption of fruits and vegetables among their clients and consumers."

This is a problem because, despite the concerns surrounding pesticide contamination, it is still better to eat fresh conventional produce than no produce at all – and currently only one in 10 Americans is meeting daily intake recommendations for fruits and vegetables. In Dr. Galligan's words, "EWG strongly encourages everyone to eat more fruits and vegetables, whether conventional or organic. Fruits and vegetables are a critical component of a healthy diet."

While it's clear that buying organic does help, the existence of the EWG's Clean Fifteen list proves that there are manageable workarounds. You can choose foods to mitigate pesticide exposure without breaking the bank, particularly if you have young children.

Dicamba Labels Challenged

Emily Unglesbee, Progressive Farmer

https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/11/10/two-commodity-groups-sue-epa-demand

ROCKVILLE, Md. (DTN) -- EPA's decision to issue 2020 labels for three dicamba herbicides was considered a win for dicamba-tolerant crop growers and their industries by many -- but not everyone is totally satisfied.

Two commodity groups are suing EPA over these newly issued labels, arguing that they are too restrictive and will hamper cotton and soybean growers' ability to control herbicide-resistant weeds in their fields.

The lawsuit, brought to the U.S. District Court for the District of Columbia by the American Soybean Association and the Plains Cotton Growers, centers around a handful of new restrictions added by EPA to the labels of XtendiMax, Engenia and Tavium herbicides. The new labels include national cutoff dates for use -- June 30 for soybeans and July 30 for cotton -- as well as larger buffers to protect neighboring areas and endangered species.

In the lawsuit, the two commodity groups framed dicamba use as some growers' remaining defense against resistant weeds. They state that cotton and soybean growers reaped "massive benefits" immediately after the initial November

2016 dicamba registrations, which didn't include those new restrictions. Without full access to dicamba, the groups concluded, "Many farms would be largely defenseless in their fight against weeds."

Farmers relieved by EPA's dicamba ruling
The Albany Herald
https://www.albanyherald.com/news/farmers-relieved-by-epas-dicamba-ruling/article_9fdb1610-22ae-11eb-9d74-dffa959f9600.html

TIFTON — The U.S. Environmental Protection Agency has approved new five-year registrations for two dicamba products and extended the registration of an additional dicamba product for use on dicamba-tolerant cotton and soybeans in a decision estimated to save growers and producers of the products millions of dollars in lost revenue.

All three registrations include new control measures to ensure these products can be used effectively while protecting the environment, including non-target plants, animals and other crops not tolerant to dicamba.

Stanley Culpepper, a professor of crop and soil sciences and University of Georgia Cooperative Extension specialist in the College of Agricultural and Environmental Sciences, said that extension personnel surveyed Georgia farmers at spring extension meetings, and 90% of growers responded that dicamba technology is important to their farming operations.

"The benefit of this technology was primarily for the control of Palmer amaranth, which is Georgia's most troublesome pest," said Culpepper, who is also a member of the National Environmentally Sound Production Agriculture Laboratory at the UGA Tifton campus. "Sharing science and information from Georgia with the U.S. EPA regarding our monumental effort to steward all pesticides has been our honor. Every member of Georgia's agricultural community should be proud of the cooperative effort in strategically improving on-target pesticide applications in ways that protect the consumer, the grower and their neighbors, and our environment."

Through the Oct. 27 action, the EPA approved new registrations for two "over-the-top" dicamba products — XtendiMax with VaporGrip Technology and Engenia Herbicide — and extended the registration for an additional OTT dicamba product, Tavium Plus VaporGrip Technology. These registrations are only for use on dicamba-tolerant (DT) cotton and soybeans and will expire in 2025.

"Farmers now have the certainty they need to make plans for their 2021 growing season," EPA Administrator Andrew Wheeler said. "After reviewing substantial amounts of new information, conducting scientific assessments based on the best available science and carefully considering input from stakeholders, we have reached a resolution that is good for our farmers and our environment."

The specified dicamba-based products have come under fire for their potential to volatilize and drift onto other crops that are not tolerant of the herbicide, causing millions of dollars in agricultural losses since the formulations were released and sparking lawsuits against manufacturers.

To manage off-site movement of dicamba, EPA's 2020 registration features important control measures, including:

— Requiring an approved pH-buffering agent (also called a volatility reduction agent or VRA) be tank-mixed with OTT dicamba products prior to all applications to control volatility;

— Requiring a downwind buffer of 240 feet and 310 feet in areas where listed species are located;

— Prohibiting OTT application of dicamba on soybeans after June 30 and cotton after July 30;

— Simplifying the label and using directions so that growers can more easily determine when and how to properly apply dicamba.

The 2020 registration labels also provide new flexibility for growers and states. For example, there are opportunities for growers to reduce the downwind spray buffer for soybeans through the use of certain approved hooded sprayers as an alternative control method. The EPA also recognizes and supports the important authority Federal Insecticide, Fungicide and Rodenticide Act section 24 gives states for issuing locally appropriate regulations for pesticide use. If a state wishes to expand the federal OTT uses of dicamba to better meet special local needs, the agency will work with them to support their goals.

This action was informed by input from state regulators, grower groups, academic researchers, pesticide manufacturers and others. The EPA reviewed substantial amounts of new information and completed Endangered Species Act effects determinations to evaluate risk on threatened wildlife within the action area.

Culpepper reported that pesticide drift complaints made to UGA Extension have dropped by 77% over the past five years, even while producers adopted dicamba- and 2,4-D-tolerant technologies across the state.

"It was truly an honor to have the U.S. EPA visit one of our top Georgia farming operations to announce the registration of several dicamba formulations that will help our growers in 2021 and beyond," he said of the Oct. 27 announcement at Cromley Farm in Brooklet.

"Also, I cannot stress enough how diligently and tirelessly the outstanding scientists at the U.S. EPA worked evaluating an enormous amount of scientific data to support their findings."

With this information and input, EPA has concluded that these registration actions meet FIFRA registration standards. EPA officials say they believe that these new analyses address the concerns expressed in regard to EPA's 2018 dicamba registrations in the June 2020 U.S. Court of Appeals for the Ninth Circuit. Further, EPA concluded that with the control measures now required on labels, these actions either do not affect or are not likely to adversely affect endangered or threatened species.

To view the final registration of the dicamba products, visit docket EPA-HQ-OPP-2020-0492 at www.regulations.gov. Learn more about pesticide safety and licensing from UGA Extension at extension.uga.edu/pesticide-safety.

In 2018, Georgia producers planted 1.49 million acres of cotton with a farm gate value of $792.7 million and 166,105 acres of soybeans with a farm gate value of $66.8 million. The U.S. is the world's leading soybean producer and second-leading soybean exporter and also serves as the world's third-largest cotton producer and the leading cotton exporter.

Today, there are limited cost-effective options to control herbicide-resistant weeds affecting these commodities. In 2018, approximately 41% of U.S. soybean acreage was planted with dicamba-tolerant seed and almost 70% of U.S. cotton acreage was planted with DT seed in 2019. Relative to alternative herbicide programs, postemergence dicamba may reduce weed control costs for some growers, possibly by as much as $10 per acre, or more than 5% of net operating revenue, not accounting for all measures growers will have to take to control off-field movement of dicamba.

Following reports of damage resulting from the off-site movement of dicamba, the EPA amended the dicamba registration labels in 2017 and in 2018. In June 2020, the U.S. Court of Appeals for the Ninth Circuit vacated the registrations for three dicamba products: XtendiMax with VaporGrip Technology, Engenia Herbicide and DuPont FeXapan Herbicide. As a result of the court's decision, the EPA issued cancellation orders outlining limited circumstances under which existing stocks of the three affected products could be distributed and used until July 31, 2020.

We Modified Crops to Kill Pests, and Pests Evolved to Adapt. Now What?
Matt Shipman, NC State University News
https://news.ncsu.edu/2020/11/preserving-utility-of-bt-crops/

For the past 25 years, U.S. farmers have been able to use genetically modified crops that produce their own pesticides. Among other things, this meant that farmers were able to grow healthy crops while applying fewer pesticides to their fields. But crop pests have begun developing resistance to genetically modifed crops, such as Bt corn and Bt cotton. So, now what?

The U.S. Environmental Protection Agency (EPA) is tasked with overseeing pesticide use. In September, EPA issued a proposal that would effectively be a first step toward revising the measures in place to ensure that these genetically modified crops remain effective against insect pests.

Scientists who study crop pests and pesticide resistance agree that something needs to be done to address pesticide resistance. The only problem? Many of those scientists say the EPA proposal may actually make things worse.

To learn more about the problem, EPA's proposal, and the concerns being raised by the research community, we spoke with Dominic Reisig, a professor of entomology and extension specialist at NC State. Reisig coordinated a coalition of agricultural extension and research scientists that has outlined an alternative strategy for addressing resistance to pesticides produced by genetically modified crops.

The Abstract: Before we talk about what's going on with EPA right now, I want to go over some of the key background ideas. First off, I see references to "Bt cotton" or "Bt corn." I know that Bt stands for Bacillus thuringiensis, but I have no idea what that means. Or what Bt cotton or corn are. Can you explain?

Dominic Reisig: Bacillus thuringiensis is a naturally occurring bacterium that can produce proteins that kill insects. Because the proteins are natural, have no human health effects, and are toxic to specific insect pests, they are used widely in organic agriculture. The terms "Bt corn" and "Bt cotton" refer to corn and cotton that have been genetically modified to produce a Bacillus thuringiensis protein that kills certain insect pests. When a plant has been genetically modified to produce an insecticide, such as the Bt protein, the insecticide is referred to as a plant incorporated protectant, or PIP.

TA: My understanding is that Bt's designation as a PIP is important, but I don't understand why. Can you explain that?

Reisig: The EPA regulates insecticide registrations, including PIPs. PIPs are special, however, in that the EPA recognizes them as a "public good." That's because PIPs can reduce the use of various insecticides, and reducing the use of those pesticides has environmental and human health benefits. So everyone can benefit from making sure PIPs remain effective against crop pests.

TA: But resistance to Bt crops is on the rise?

Reisig: Unfortunately, yes. To prevent insects from developing resistance to Bt proteins, PIPs rely on the high-dose/refuge strategy. It's pretty complex, but the simple version works like this: for a high-dose insect pest, it takes very little Bt protein to kill the insect and there aren't many resistant insects present in the population. (And, yes, it's counter-intuitive that "high-dose" pests are killed by low doses of Bt. But that's the terminology.) Refuge is provided to these pests, essentially meaning that you give those pests a certain amount of territory where they can prosper. This means that there will always be "vulnerable" pests that are fit in every way – but have not developed resistance to Bt crops. Those fit, but vulnerable, pests will be able to breed with any pests that are developing resistance to Bt crops. In this way, resistance genes are drowned out of the population.

Commercially, two types of Bt proteins are used as PIPs, crystalline (Cry) and vegetative insecticidal (Vip) proteins. The first Bt crops were commercially planted during 1996; by 2016, there were 16 cases of resistance to Cry proteins, but no cases of resistance to Vip proteins.

Here's where things get a little tricky to explain. The EPA defines a "high dose" as a PIP that produces a level of toxin that is 25 times greater than is needed to kill all susceptible insects. Pests that fit this definition were later called "high-dose pests." (This explains why pests that are sensitive to Bt are called high-dose pests, even though that seems

counter-intuitive.) In hindsight, the high-dose/refuge strategy worked very well for high-dose pests, but not for all pests. Those 16 cases of Cry resistance happened for "non-high-dose pests," which were less sensitive to the Bt toxin.

TA: So, what is EPA doing to preserve the public good and address the increase in resistance to Bt crops?

Reisig: The EPA recognized that the current framework to delay resistance worked well for high-dose pests, but not for non-high-dose pests. Therefore, they convened a scientific advisory panel to develop a white paper on how improve resistance management for non-high-dose caterpillar pests during 2018. Recently, the EPA released a proposal to change the resistance management framework for non-high-dose caterpillar pests. [Public comment on the proposal closed Nov. 9.] EPA's proposal applies to caterpillar pests that don't fit the description of high-dose pests, which I explained a minute ago. Specifically, for these caterpillar pests, EPA is proposing to change the way that resistance in the field is defined, to outline a better way to detect resistance, to find a way to mitigate resistance once it occurs, and is seeking comment on ways to mitigate risk of resistance by changing which PIPs can be planted and how refuge is planted.

TA: You worked with university-based agricultural entomologists from across the country to weigh in on the proposal. Before addressing your feedback on the proposal, can you explain what a university-based agricultural entomologist is?

Reisig: Sure, our group works with insects of importance to agriculture: both pests, like the proverbial boll weevil, and beneficial species, such as pollinators. Some of us are field-based, while some of us are lab-based. Some of us work directly with the insects, while others of us work almost exclusively with genetics. So we are a very diverse group.

On this issue, I worked with corn and cotton entomologists, most of us being from U.S. land-grant universities, as well as some of our Canadian colleagues. Our job is to bring science-based information to stakeholders in the agriculture community to enhance profitability and protect the environment and human health.

TA: What are the concerns that agricultural entomologists have with the proposal?

Reisig: While we are pleased that the EPA is concerned about maintaining the efficacy of PIPs for non-high-dose pests, we think that the proposal strays from the recommendations of the 2018 scientific advisory panel in many important ways. As it stands, we predict that implementing this proposal will lead to the rapid and intense development of resistance to Vip proteins in two nationally important insect pests: bollworm (corn earworm) and western bean cutworm.

TA: Why is this important?

Reisig: Based on past experiences with PIP resistance, the growers and the environment will bear the brunt of the costs. When resistance occurs, growers have to pay more for additional insecticides to try to eliminate the insect pests. Growers may also incur additional burdens, such as having to destroy all of the plantings in a field and tilling it under. And the environmental benefits of using the PIP would be completely lost.

Furthermore, the initial framework to manage PIP resistance has been in place for 24 years. If this new framework is adopted, it will apply not only to PIPs in plants that are grown right now, but to any future PIPs that are registered and planted, potentially for a very long time.

TA: But you're not just highlighting the problem, you're proposing a solution, right? What does that look like?

Reisig: Absolutely. In our response, we worked hard to pull from the best available science to provide suggestions that can effectively delay resistance. There are some scientific gaps in our knowledge, such as knowing how to best detect resistance in the field. We point these out and are working hard as a group to address these areas. However, our proposed solution is based on the first principles of resistance management: 1) limit use of the insecticide; 2) diversify use of the insecticide; and 3) break up use of the insecticide in space and time to produce refuges.

TA: So, what happens next?

Reisig: The EPA will evaluate all of the public comments and finalize their recommendations. They will work with the seed providers (who own the PIPs) to fill out details that are lacking. At this point, however, we don't know what the final recommendations will be.

EPA Seeks Participants for Small Business Review Panel on HBCD Risk Management Rulemaking
Lynn L. Bergeson & Carla N. Hutton, B&C TSCA Blog
http://www.tscablog.com/entry/epa-seeks-participants-for-small-business-review-panel-on-hbcd-risk-managem

The U.S. Environmental Protection Agency (EPA) announced on November 9, 2020, that it is inviting small businesses, governments, and not-for-profits to participate as Small Entity Representatives (SER) to provide advice and recommendations to a Small Business Advocacy Review (SBAR) Panel for the cyclic aliphatic bromide cluster (HBCD). The Panel will focus on EPA's development of a proposed rule to address unreasonable risks identified in EPA's recently completed Toxic Substances Control Act (TSCA) risk evaluation for HBCD. As reported in our September 28, 2020, memorandum, EPA found unreasonable risks to the environment from six out of 12 conditions of use and unreasonable risks to workers and occupational non-users (ONU) from the processing, use, and disposal of HBCD, largely from building and construction materials. EPA's website states "EPA did not find unreasonable risks to the general population or consumers." Nevertheless, in the risk evaluation document, EPA did find unreasonable risk from fish ingestion at the high-end exposure in one scenario. EPA is now moving to the risk management step in the TSCA process by working to draft regulations to protect public health from the unreasonable risks identified in the final risk evaluation.

According to EPA, the Regulatory Flexibility Act requires agencies to establish an SBAR Panel for rules that may have a significant economic impact on a substantial number of small entities. The SBAR Panel will include federal representatives from the Small Business Administration (SBA), the Office of Management and Budget (OMB), and EPA. The SBAR Panel will select SERs to provide comments on behalf of their company, community, or organization and advise the Panel on the potential impacts of the proposed rule on small entities. EPA states that it is seeking self-nominations directly from the small entities that may be subject to the rule's requirements. EPA notes that other representatives, such as trade associations that exclusively or at least primarily represent potentially regulated small entities, may also serve as SERs. Self-nominations may be submitted online and must be received by November 23, 2020.

EPA states that in addition to engaging with small businesses, it "is executing a robust outreach effort on risk management that includes one-on-one meetings with stakeholders and formal consultations with state and local governments, tribes, and environmental justice communities." EPA notes that there will also be an open public comment period on any draft risk management regulation.

EPA Seeks Participants for Small Business Review Panel on HBCD Risk Management Rulemaking
Lynn L. Bergeson & Carla N. Hutton, National Law Review (B&C)
https://www.natlawreview.com/article/epa-seeks-participants-small-business-review-panel-hbcd-risk-management-rulemaking

The U.S. Environmental Protection Agency (EPA) announced on November 9, 2020, that it is inviting small businesses, governments, and not-for-profits to participate as Small Entity Representatives (SER) to provide advice and recommendations to a Small Business Advocacy Review (SBAR) Panel for the cyclic aliphatic bromide cluster (HBCD). The Panel will focus on EPA's development of a proposed rule to address unreasonable risks identified in EPA's recently completed Toxic Substances Control Act (TSCA) risk evaluation for HBCD. As reported in our September 28, 2020, memorandum, EPA found unreasonable risks to the environment from six out of 12 conditions of use and unreasonable risks to workers and occupational non-users (ONU) from the processing, use, and disposal of HBCD, largely from building and construction materials. EPA's website states "EPA did not find unreasonable risks to the general population or consumers." Nevertheless, in the risk evaluation document, EPA did find unreasonable risk from fish ingestion at the high-end exposure in one scenario. EPA is now moving to the risk management step in the TSCA process by working to draft regulations to protect public health from the unreasonable risks identified in the final risk evaluation.

According to EPA, the Regulatory Flexibility Act requires agencies to establish an SBAR Panel for rules that may have a significant economic impact on a substantial number of small entities. The SBAR Panel will include federal representatives from the Small Business Administration (SBA), the Office of Management and Budget (OMB), and EPA. The SBAR Panel will select SERs to provide comments on behalf of their company, community, or organization and advise the Panel on the potential impacts of the proposed rule on small entities. EPA states that it is seeking self-nominations directly from the small entities that may be subject to the rule's requirements. EPA notes that other representatives, such as trade associations that exclusively or at least primarily represent potentially regulated small entities, may also serve as SERs. Self-nominations may be submitted online and must be received by November 23, 2020.

EPA states that in addition to engaging with small businesses, it "is executing a robust outreach effort on risk management that includes one-on-one meetings with stakeholders and formal consultations with state and local governments, tribes, and environmental justice communities." EPA notes that there will also be an open public comment period on any draft risk management regulation.

How Will the Biden Administration Tackle 'Forever Chemicals'?
Scott Faber, Environmental Working Group
https://www.ewg.org/news-and-analysis/2020/11/how-will-biden-administration-tackle-forever-chemicals

No candidate for president has ever pledged to make the toxic "forever chemicals" known as PFAS a priority – until now.

In his environmental justice plan, President-elect Joe Biden pledged to set enforceable limits for PFAS in drinking water and to designate PFAS as a hazardous substance under the Superfund cleanup law.

Here's why that matters.

PFAS chemicals are building up in the blood of every American, posing the risk of serious health problems. PFAS makes vaccines less effective and are linked to cancer, harm to the reproductive system and other health hazards.

More than 200 million Americans are likely drinking water and eating food contaminated with PFAS. Nevertheless, the Environmental Protection Agency, Food and Drug Administration and Defense Department have for decades failed to address the chemicals' health risks. There are no federal limits on PFAS releases and uses and no requirements to clean up PFAS pollution.

Setting a national drinking water standard for PFAS under the federal Safe Drinking Water would have a huge impact on public health. Right now, only a few states require drinking water utilities to meet tough standards for PFAS in tap water. A national standard that would apply to all utilities would dramatically reduce our overall exposure to PFAS.

Designating PFAS as "hazardous substances" under Superfund would also be historic. By doing so, the Biden-Harris administration would not only kick-start the cleanup process but also require polluters to pay their fair share of cleanup costs.

But that's not all the Biden team has pledged. The president-elect also pledged to prioritize PFAS substitutes in the marketplace. That means Biden could direct the EPA and the FDA to quickly phase out non-essential uses of PFAS in food packaging, cosmetics, sunscreens and other everyday products.

The Biden team will have other tools at its disposal. The president-elect could quickly restrict industrial discharges of PFAS into the air and water by using the tools provided by the Clean Air Act and the Clean Water Act, and expand reporting of these releases through the Toxic Release Inventory. Right now, more than 2,500 manufacturers are thought to be releasing PFAS with no limits.

The Biden-Harris administration can also direct the Defense Department to accelerate efforts to end the use of PFAS-based firefighting foam, impose a moratorium on the incineration of remaining stocks of PFAS foam, and accelerate PFAS cleanup at military installations. More than 300 military installations are known to be contaminated with PFAS.

No candidates have ever pledged to do as much to address America's environmental challenges as Joe Biden and Kamala Harris. And that is especially the case for PFAS pollution.

Lung Cancer Awareness Month: A Plea to Ban Asbestos

Devin Golden

https://www.mesotheliomaguide.com/community/lung-cancer-awareness-month-house-passing-asbestos-ban-bill/

The U.S. House of Representatives had an opportunity one month ago to make a statement: The health of Americans is a priority. The action before them — whether or not to ban asbestos — seemed like a no-brainer.

However, in the last week of September, the legislative body let us down. They put party-line politics ahead of Americans' well-being.

The House is about to go back in session. According to the official calendar, the body will vote on resolutions next week, Nov. 16-20. Those five days present another chance to pass the Alan Reinstein Ban Asbestos Now Act of 2020, which should be a book-closing moment on a decades-long American health crisis.

There's an extra layer of symbolism this time. The House can make headlines by passing the bill during Lung Cancer Awareness Month.

Asbestos started with the label of "magic mineral" in the mid-20th century. It was prioritized for constructing houses, offices, automobiles, military ships and more. Now it holds a "cancerous" reputation, the sole cause of mesothelioma and a potential source of lung cancer.

The statistics should be enough to convince Congress it's long past time to outlaw asbestos. According to Asbestos Nation, between 12,000 and 15,000 people in America die each year from asbestos diseases. Mesothelioma accounts for around 3,000 while lung cancer is attributed to 12,000 deaths.

Asbestos is dangerous when inhaled or swallowed. The concern is people rarely can tell when either occurs. Asbestos is so small that people won't see it floating in the air in front of them. A simple inhalation could be deadly.

When it enters the body, asbestos can attack the tissue on the lungs and cause cancer to form on the organ. Sometimes asbestos enters the narrow lining near the lungs (pleura) or the lining around the abdomen (peritoneum), the two locations where mesothelioma forms. This mineral can also cause asbestosis, a deadly lung disease characterized by tissue scarring.

Most industries have distanced themselves from such a notorious (for all the wrong reasons) substance. They've found alternatives, and the Environmental Protection Agency has added its own restrictions. Still, the door for a resurgence remains cracked open.

Some believe only specific types of asbestos are dangerous, while others are still usable. Those beliefs could add to the death toll, and they're more reason to ban asbestos once and for all.

Yet, in September, the House of Representatives had the Alan Reinstein Ban Asbestos Now Act on the agenda. They then pulled it when cross-party support faded at the 11th hour.

The explanation fell right in line with frustrating American politics, where each side pointed blame at the other. For at least two more months, asbestos was legal. Companies hoping for an asbestos comeback could hold out dangerous hope.

The House has another chance to right the wrong from September — and from the past century-plus of deadly exposure. Lung Cancer Awareness Month would be a fitting time to ban a substance that causes thousands of lung cancer deaths each year.

Even if the vote doesn't occur in the next session, we hope it's very soon. America got closer than ever in September to taking a massive step towards an asbestos ban. Every legislative session brings another opportunity, with another round of hope.

Right now, our hope lies with next week. Passing this bill during Lung Cancer Awareness Month is too perfect to pass up.

++

For more news, visit:

- Inside EPA: https://insideepa.com/
- Inside TSCA: https://insideepa.com/inside-tsca-home
- Bloomberg Environment and Energy: https://news.bloombergenvironment.com/environment-and-energy/

If you'd like to be removed or would like to add someone to the listserv please contact Bailey Rosen at Rosen.Bailey@epa.gov. Feedback and interesting articles are welcomed. Thanks and enjoy!

And while you're reading…. Remember to shoot your coworkers a shooting star!